

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 0-01 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-D-12-050		Contract Period 08/02/2012 To 08/01/2013 Base <input checked="" type="checkbox"/> Option Period Number								
Contractor WESTAT, INC.		Title of Work Assignment/SF Site Name 0-01 Water and Human Health								
Specify Section and paragraph of Contract SOW Sections 1.1, 1.2, 2.3, 2.4										
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 08/02/2012 To 08/01/2013								
Comments: SEE ATTACHED SOW. THE CONTRACTOR SHALL NOT DUPLICATE ANY WORK PREVIOUSLY PERFORMED OR INCUR ANY COST PREVIOUSLY INCURRED UNDER ANY OTHER WORK ASSIGNMENT PERFORMED UNDER THIS OR THE PREVIOUS CONTRACT (EP-D-07-109).										
<input type="checkbox"/> Superfund		Accounting and Appropriations Data								
		<input checked="" type="checkbox"/> Non-Superfund								
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
08/02/2012 To 08/01/2013				0						
This Action:				290						
Total:				290						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:		LOE:				
Cumulative Approved:				Cost/Fee:		LOE:				
Work Assignment Manager Name Edward Hudgens						Branch/Mail Code:				
_____ (Signature) _____ (Date)						Phone Number 919-966-0642				
						FAX Number:				
Project Officer Name Ann H. Williams						Branch/Mail Code:				
_____ (Signature) _____ (Date)						Phone Number: 919-843-4833				
						FAX Number:				
Other Agency Official Name						Branch/Mail Code:				
_____ (Signature) _____ (Date)						Phone Number:				
						FAX Number:				
Contracting Official Name Marsha B. Johnson						Branch/Mail Code:				
_____ (Signature) _____ (Date)						Phone Number: 919-541-0952				
						FAX Number:				

0-01: Support for Water and Human Health Studies WORK ASSIGNMENT STATEMENT OF WORK

I. Background and Objectives

This statement of work is designed to continue the efforts begun during the previous Work Assignments on the previous Epidemiology Support Contracts (Contracts EP-D-07-109 and 68-D-02-062). Westat, Inc. shall not duplicate work performed for these earlier work assignments and shall utilize materials previously prepared as templates for future work. In particular, Westat shall take full advantage of the Quality Assurance Project Plans, Data Management Plans, Database Documentation, Statistical Recommendations and Deliverables developed / submitted previously.

The Environmental Public Health Division (EPHD) conducts clinical and epidemiological research to improve the understanding of human health risks associated with exposure to drinking water contaminants and pathogenic organisms. Epidemiologic investigations study humans in less rigidly controlled, more natural settings by field studies or analysis of existing data. Biomarker methods for exposure, dose and susceptibility will be developed for and applied to a range of health effects including cancer, reproductive effects, cardiovascular disease, and respiratory effects. Laboratory analyses are used to improve assessments of exposure, biologically relevant doses, adverse biological or health effects, as well as to investigate mechanisms linking these phenomena. Studies are frequently designed and analyzed so as to characterize the similarities or differences between effects observed in humans and animals or in vitro systems; the data are then used by the Agency for risk assessment in the absence of human data. Investigations conducted by this division frequently involve collaborations within and outside the Agency, and emphasize interdisciplinary approaches that integrate complex data from existing records, questionnaires, clinical, and laboratory studies.

Database management, review of the results of previous statistical requests, statistical data analyses, spatial analyses, peer reviews of draft documents and review of the scientific literature are fundamental components for these activities. Additionally, a literature review is a significant component of any research paper submitted for publication in a peer-reviewed journal. Such a review may include studies from many scientific disciplines, including epidemiology, toxicology, ecology, exposure assessment, dosimetry and hydrology.

In addition to steps listed above, manuscript preparation requires the drafting of data tables and figures, and report or journal article sections including introduction, methods and materials, results, discussion, conclusions, acknowledgements, and literature cited. The EPA will provide materials such as data, outlines and rough drafts of manuscripts to be used as the basis for a literature review and final manuscript drafting.

The main objective of this work assignment is to support various Water and Human Health studies by analyzing and preparing data and materials for publication or for the support of future field collection efforts.

II. Task Descriptions

Task 1. In previous Work Assignments, the Contractor provided statistical, editorial and graphics support for two manuscripts that presented results from the Nevada Arsenic Study. The Contractor completed a scientific and editorial review of a draft manuscript of the Nevada Arsenic Study Overview Paper which has been submitted to *Environmental Research*. The Contractor shall review any future draft based on journal reviewers' comments and shall provide comments to improve the editorial quality, clarity and / or validity of the scientific conclusions. If altered by the EPA, the Contractor shall review previously submitted statistical methodology sections for accuracy and completeness. The Contractor shall prepare new versions of existing data tables and figures, when necessary, for the manuscript. While the EPA does not anticipate any changes in the number or types of graphics in the draft manuscript, the WACOR will dictate the appropriate number and types of presentations through technical direction.

The EPA will provide the Contractor with a draft manuscript of the Nevada Arsenic Study Metabolism and Genetic Polymorphism Paper which is intended for submission to a scientific journal such as *Environmental Health Perspectives*. The Contractor shall update data analysis results provided under previous Task Orders or Work Assignments, if necessary. The Contractor shall document any differences between earlier analysis results and the results of the new data analyses. Since one of the major discussion areas in this manuscript is the relationship between genetic differences and arsenic metabolism in 200 individuals using the genetic data added during the previous Work Assignments, the Contractor shall be prepared to add the results of other genetic analyses and to perform additional analyses of this information. The Contractor shall ensure that all tables and figures in this draft either accurately reflect the updated data analysis results or provide revised versions of the graphics in a format suitable for journal submission. The Contractor shall prepare graphics to illustrate the results of this analysis work. Once the EPA researchers have completed the incorporation of any new or updated materials into the draft paper, the Contractor shall review the draft and shall provide comments to improve the editorial quality, clarity and / or validity of the scientific conclusions. The Contractor shall review previously submitted statistical methodology sections for accuracy and completeness.

The Contractor shall maintain liaison with the WACOR through conference calls, at an agreed upon interval, regarding the status of the activities within this Task. The Contractor shall prepare Agendas for the conference calls, distribute the Action Items and distribute Action Item updates during weeks without conference calls. Copies of all deliverables shall be sent to the WACOR, the COR and the CO (as necessary).

Task 2. As part of Contract EP-D-07-109's WA 4-01 (Water), the Contractor conducted a literature search and assembled a database of references of epidemiological studies examining the human health effects associated with surface coal mining operations in

Appalachia. The Contractor prepared a report reviewing, summarizing and assessing the quality of the assembled literature and conducted a peer review of the draft report. For this Task, the Contractor shall prepare a response to the peer reviewers' comments document of no greater than 5 pages of original text. The Contractor shall sort and arrange the reviewers' comments so that similar comments are addressed with a single response. The Contractor shall edit and amend the draft report based on their response to the reviewers' comments, as needed. The Contractor shall be prepared to write a description of the epidemiology concepts and study designs presented in the draft report for individuals that do not have an advanced knowledge of epidemiology (also referred to as a "primer"). This primer shall not exceed 5 pages in length. The Contractor shall be prepared to produce a glossary of terms used in the draft report. This glossary shall not exceed 5 pages in length. The WACOR will provide additional guidance on the level of detail required in the primer and glossary through Technical Direction.

The Contractor shall maintain liaison with the WACOR through conference calls, at an agreed upon interval, regarding the status of the activities within this Task. The Contractor shall prepare Agendas for the conference calls, distribute the Action Items and distribute Action Item updates during weeks without conference calls. Copies of all deliverables shall be sent to the WACOR, the COR and the CO (upon request).

III. Deliverables

Special reporting requirements include documentation of all sources and contacts so as to fully reference the sources of all information. The Contractor shall submit to the Work Assignment Contracting Officer's Representative (WACOR) the following deliverables:

Task 1,2. Deliverable 1. A detailed Work Plan, in response to the Tasks within this Work Assignment, shall be due 20 calendar days from the effective date of this Work Assignment for review by the Work Assignment Contracting Officer Representative (WACOR), Contracting Officer Representative (COR), and the Contracting Officer (CO). As part of this Work Plan, the Contractor shall also prepare a cost estimate for accomplishment of the Tasks within this Work Assignment. The Contractor shall also supply relevant information on the roles and responsibilities of any subcontractor. The content of the detailed Work Plan shall be in accordance with the terms of the contract and responsive to the requirements of this Work Assignment.

Deliverable 2. The Contractor shall prepare monthly progress reports pursuant to the terms of the contract, monitor the budget and administer these Tasks through their completion. The Contractor shall coordinate their reports and administration duties across all of the Tasks within this Work Assignment.

Deliverable 3. The Contractor shall prepare a final report summarizing all analyses, recommendations, reports, or comments provided for each Task during the Period of Performance of this Work Assignment. The final report shall provide documentation for any electronic data sets that may have been generated. Updated versions of any

amended databases, data dictionaries, data sets, programs or documents, as well as all graphics and tables generated during the Work Assignment, are due at the completion of the work assignment and in a format that has been approved by the WACOR. Copies of the Monthly Reports, conference call Agendas and the agreed upon Action Items shall be included as documentation of each Task's and the overall Work Assignment's course and progress. This report shall include suggestions for potential future work or improvements to the deliverables for any Task that has not been completed during the Period of Performance of this Work Assignment. A draft report is due 14 calendar days before the end of the Work Assignment. A final report, incorporating any EPA comments, is due at the end of the Work Assignment. Files submitted on CD or DVD shall have an accompanying Table of Contents in a format that has been approved by the WACOR.

- Task 1. Deliverable 4.** The Contractor shall review the draft of the Nevada Arsenic Study Overview Paper which incorporates reviewer comments and shall provide comments to improve the editorial quality, clarity and / or validity of the scientific conclusions within 21 calendar days of receipt. The Contractor shall review previously submitted statistical methodology sections for accuracy and completeness, provide comments, document any changes and the rationale for the change. The Contractor shall review existing data tables and figures and prepare new versions, when necessary, for the manuscript.
- Task 1. Deliverable 5.** The Contractor shall review the draft of the Nevada Arsenic Study Metabolism and Genetic Polymorphism Paper and shall provide comments to improve the editorial quality, clarity and / or validity of the scientific conclusions within 21 calendar days of receipt, prior to its submission to a peer reviewed journal. The Contractor shall review previously submitted statistical methodology sections for accuracy and completeness, provide comments, document any changes and the rationale for the change. The Contractor shall review existing data tables and figures and prepare new versions, when necessary, for the manuscript.
- Task 2. Deliverable 6.** The Contractor shall prepare a draft response to the peer reviewers' comments document of no greater than 5 pages of original text within 21 calendar days of receipt of this Work Assignment. The EPA will provide comments on the draft document within 14 calendar days after receipt. A final report, incorporating any EPA comments, is due within 14 calendar days of receipt of the EPA's comments. The Contractor shall deliver the final response document and all supporting documentation in a format that has been approved by the WACOR.
- Task 2. Deliverable 7.** The Contractor shall edit and amend the draft report on the health effects of surface coal mining in Appalachia based on their response to the reviewers' comments, as needed. The Contractor shall include a primer and a glossary of terms, if required. The EPA will provide comments on the amended document within 21 calendar days after receipt. A final report, incorporating any EPA comments, is due within 14 calendar days of receipt of the EPA's comments. The Contractor shall deliver the final response document and all supporting documentation in a format that

has been approved by the WACOR. This draft report shall be finalized within four months of the receipt of this Work Assignment.

IV. Reporting Requirements

The Contractor shall furnish a copy of the Work Plan, as well as each section of the combined monthly technical and financial progress reports which relate to this Work Assignment directly to the Work Assignment Contracting Officer Representative at the same time progress reports are submitted to the Contracting Officer Representative and Contracting Officer. The work plan shall serve as the QAPP for this Work Assignment.

Special reporting requirements include documentation of all sources so as to fully reference the sources of all information. Deliverables shall be provided in hard copy and electronically on CD-ROM, DVD or via email. Reports shall be written in Word or PDF format, based upon approval from the WACOR. Two copies of the final report shall be provided to the WACOR. A copy to of the final report shall be provided to the COR and CO, upon request.

V. Work Assignment Contracting Officer's Representative Designation

The Work Assignment Contracting Officer's Representative (WACOR) will be:

Edward E. Hudgens
Chemist
US EPA/ORD/NHEERL/EPHD/EB (MD-58C)
Research Triangle Park, NC 27711
Telephone: 919-966-0642
Fax : 919-966-0655
Email: hudgens.edward@epa.gov

The preferred method of contact is by email.

VI. WORK ASSIGNMENT DURATION

The period of performance for this work assignment is from date of issuance through February 28, 2013.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

The contractor shall not engage in activities of an inherently governmental nature such as the following:

1. Formulation of Agency policy;
2. Selection of Agency priorities;
3. Development of Agency regulations.

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the COR or the Contract Officer.

The contractor shall also ensure that the work under each individual work assignment does not contain any real or apparent personal or organizational conflict of interest. The contractor shall certify that none exist at the time the work plan is submitted to the EPA.